Science Policy Note SPN2017-02

Joint Canada/United States Field Trial Requirements

(publié aussi en français)

11 July 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 2368-1861 (online)

Catalogue number: H113-13/2017-2E-PDF (PDF version)

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Table of contents

Guidelines for Reduced Residue Field Trial Requirements to Support Joint Projects Between Canada and the United States 1
1.0 Purpose 1
2.0 Background 1
3.0 Crop Selection 2
4.0 Determination of the Number of Field Trials by Crop 2
5.0 Distribution of Trials Across North America 3
6.0 Use of Reduced Trial Requirements 4
7.0 Codex Maximum Residue Limits and Other International Harmonization Considerations 4
Appendix I Table of distribution of Trial Requirements for Joint Canadian/American Projects 7
Table 2 Distribution of Trial Requirements for Joint Canadian/American Projects 7
Appendix II Table of Percentage Reduction for Joint Canadian/American Projects for Crop Field Trial Requirements 11
Table 3 Percentage Reduction (% Reduction) in Trial Requirements When Total Country Specific Requirements for United States and Canada are Compared to Total Requirements for a Joint American/Canadian Project 11
References 13

Guidelines for Reduced Residue Field Trial Requirements to Support Joint Projects Between Canada and the United States

1.0 Purpose

The purpose of this document is to communicate to industry and other interested parties, the revised crop trial requirements for trials that are conducted to support simultaneous domestic registration applications in both Canada and the United States.

2.0 Background

Through the collaborative work between the United States' Interregional Research Project #4 and Canada's Pest Management Centre of Agriculture and Agri-Food Canada, on an ad-hoc basis, these organizations have submitted residue trial reduction proposals to the Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (USEPA) for joint projects which required residue data to be generated. These proposals were jointly reviewed, discussed, and revised as necessary to ensure that both Agencies were in agreement with the revised residue program.

By sharing resources and developing data jointly, the minor use programs have been able to provide growers in Canada and in the United States with the same crop protection technology at approximately the same time, with the same maximum residue limits (MRLs)/tolerances. However, for some commodities, the data requirements for the joint studies can be excessive as the number of trials required is based on the total number of trials required by the USEPA and trials required by the PMRA. If there is little overlap between countries, in terms of where these trials must be conducted, there are minimal savings realized for a joint project. In addition, the Canadian and American trial requirements as outlined in the PMRA's Regulatory Directive DIR2010-05, *Revisions to the Residue Chemistry Crop Field Trial Requirements* (December 2010) and the USEPA Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 860.1500 (*Crop Field Trials*), respectively, are based principally on country-specific production and modified by consideration of percent dietary share (see Section 4). Because each country applies the percent dietary share to their production figures individually, when summing the trial requirements for joint American/Canadian residue programs, the dietary share is, in effect, considered twice. This does not occur if the American/Canadian production is combined prior to application of the percent dietary share.

In the context of joint residue trial projects intended to support simultaneous domestic registration applications in both the United States and Canada, the USEPA and PMRA have re-assessed the trial requirements for the representative crops in the NAFTA Residue Chemistry Crop Groups (see 40 CFR 180.41 and PMRA website [Residue Chemistry Crop Groups - Pesticides and Food - Health Canada]). In addition, key minor or specialty crops of importance to growers in both countries have also been included in the trial requirement assessment. It is expected that the reduction in the number of trials required for joint projects will allow both the minor use programs as well as pesticide Registrants to use their resources more efficiently, leading to an increase in joint American/Canadian registrations. In addition, it may also help to meet the criteria for trial distinction/separation by allocating fewer field trials across the available geographic range. It is noted that no further reductions (for example, a 25% reduction for a crop group) can be applied to these trial requirements.

3.0 Crop Selection

Crop trial requirements that had been previously established by the PMRA and USEPA were compared and a list was compiled of those crops that had requirements specified in both countries. Using the USEPA/PMRA crop grouping scheme, which includes representative crops for each crop group, the list was refined so that it only included representative crops. This list was used as the basis for this trial reduction project and no changes were made to the representative crops. In addition, United States' Interregional Research Project #4 and Canada's Pest Management Centre were consulted to identify any minor/specialty crops of interest to growers that would benefit from joint work between the United States and Canada.

Greenhouse grown crops were not considered in the scope of this project. Given the controlled environment within a greenhouse, the geographical distribution of the trials is not a concern.

The Crop Group names in this document refer to the Canadian designations. The American designations are found in the United States Code of Federal Regulations, Title 40, Part 180, Subpart 41.

Crop Groups 10 (Revised), 14-11, 17, 18, 19, 20C (Revised), 21, 23 and 24 were not included for the following reasons:

- Crop Group 10 (Revised) (Citrus Fruits), Crop Subgroup 20C (Revised) (Cottonseeds), Crop Group 23 (Tropical and Subtropical Fruits – Edible Peel Group) and Crop Group 24 (Tropical and Subtropical Fruits – Inedible Peel Group) were not included because crops in these crop groups are not grown in Canada.
- Crop Group 14-11 (Tree Nuts) was not included due to the low acreage of tree nuts grown in Canada.
- Crop Group 17 (Grass forage, fodder, and Hay Group) and Crop Group 18 (Nongrass Animal Feeds) were not included as this project only considered food crops and not feed crops.
- Crop Group 19 (Herbs and Spices) was not included as this crop group is currently under revision; furthermore, it is expected that the representative crops will change and the group will be divided into two groups.
- Crop Group 21 (Edible Fungi) was also not included since the majority of the production of mushrooms occurs in greenhouses or mushroom houses, and geographic distribution is not a concern.

4.0 Determination of the Number of Field Trials by Crop

For each crop, the total Canadian production (DIR2010-05, Table 1.1) was added to the total American production (Methodology Report).[1] This combined total production was then used to assign a total base number of field trials for a Canada/United States joint project (Table 1). The Canadian production was based on Statistics Canada 2006 Census of Agriculture while the

[1] *Methodology Report – Updating the Number and Location of crop Field Trials for the United States of America*. May 2007. Spatial Analysis and Geomatics Applications (SAGA), Agriculture Division, Statistics Canada. 206 pages.

American production was from the United States 2002 Census of Agriculture, after comparison to 2007 production figures.[2] For edible podded and succulent shelled peas and beans, more recent Canadian and American production data from 2012 to 2016 were used because the older census data did not differentiate the different bean and pea varieties.

Table 1 Base Number of Field Trials

Area in Hectares	Area in Acres	Base Number of Field Trials
> 4,046,860	> 10,000,000	16
> 404,690 ≤ 4,046,860	> 1,000,000 ≤ 10,000,000	12
> 121,410 ≤ 404,690	> 300,000 ≤ 1,000,000	8
> 12,140 ≤ 121,410	> 30,000 ≤ 300,000	5
> 810 ≤ 12,140	> 2000 ≤ 30,000	3
> 81 ≤ 810	> 200 ≤ 2000	2
≤ 81	≤ 200	1

The base number of trials were then increased or decreased depending on the dietary share of the crop based on consumption by the general population (Criteria outlined below). The dietary share information was obtained from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998, which is summarized in the NAFTA Guidance Document on Data Requirements for Tolerances on Imported commodities in the United States and Canada (2005).

Criteria:

- Increase the base number one level, such as, 8 to 12 or 12 to 16, etc., if the area exceeds 121,410 hectares (300,000 acres) and the dietary share is 0.40% or more.
- Decrease the base number one level if the area exceeds 121,410 hectares (300,000 acres) and the dietary share is less than 0.10%.
- Increase the base number one level if the area is 121,410 hectares (300,000 acres) or less and the dietary share is 0.02% or more.
- A minimum of 16 field trials is required for crops of more than 121,410 hectares (300,000 acres) and a dietary share of more than 1.00%.
- A minimum of 12 field trials is required for crops 121,410 hectares (300,000 acres) or less and dietary share of more than 1.00%.

5.0 Distribution of Trials Across North America

The total crop production for each region or zone was calculated and converted into a percentage to determine the percentage of trials for that region (the percentage of trials is equal to the total production for that region divided by the total production for all regions (area planted)).

[2] The USEPA compared the 2002 data to the more recent 2007 census information to ensure that the 2002 data were a valid representation of the more recent crop production figures. There were no significant changes to crop production area or geographic distribution between 2002 and 2007.

The number of trials per region was then calculated by multiplying the percentage of trials in that region by the total number of required trials. Final distribution of the trials and the number required in each region was then selected based on rounding up or down to the nearest whole number.

The caveats that there must be a minimum of four trials for each crop and that the trial distribution must include at least two trials in the major production regions of each country were then applied.

Appendix I lists the trial requirements for residue programs that are required to support domestic registration applications in both Canada and the United States. Note that growing regions 5, 5A, and 5B are listed as the single growing region 5. Trials may be conducted in 5, 5A, or 5B to address growing region 5 requirements. Growing Regions 7 and 7A are listed separately as they are considered distinct regions due to the irrigation practices in region 7A. As a result of irrigation, many vegetable crops are grown in 7A that cannot be grown in 7. Appendix II lists the crops that were considered for trial reductions and the percentage reduction as compared to the overall trial requirements when the separate American and Canadian requirements are added together. Note that the percentage reduction does not take into consideration any overlap between regions common to both countries.

6.0 Use of Reduced Trial Requirements

The trial requirements as outlined in this guidance document apply only to projects that will be conducted to support a joint registration in both the United States and Canada. Deviations from these requirements will be considered on a case-by-case basis and must be discussed and agreed to by both the PMRA and the USEPA. If trials are being conducted to support a domestic registration in only the United States or Canada, then the country specific requirements apply. For Canada, the number and geographic distributions of field trial requirements to support a domestic registration are outlined in DIR2010-05, *Revision to the Residue Chemistry Crop Field Trial Requirements*; for the United States, the requirements are found in OCSPP Guideline 860.1500.

7.0 Codex Maximum Residue Limits and Other International Harmonization Considerations

The field trial requirements specified in this document are intended to ensure an adequate number of trials to support joint Canadian-American registration applications. If petitioners intend to seek Codex Maximum Residue Limits, additional trials may be necessary to meet Codex requirements. In the Report of the 47th Session of the Codex Committee on Pesticide Residues (CCPR; REP15/PR), minor crops are divided into three categories based on worldwide and GEMS Food Cluster consumption estimates:

> Category 1: No data; number of trials to be considered on a case-by-case basis
> Category 2: <0.5% worldwide and <0.5% in all of the food clusters = at least four trials
> Category 3: <0.5% worldwide and >0.5% in one or more food cluster = at least five trials

On that basis, the Joint Meeting on Pesticide Residues (JMPR) established that "a minimum number of four independent supervised field trials reflecting the respective GAPs for Category 1 and Category 2 crops and five trials according to Category 3 crops will be used as the basis for

recommending maximum residue levels. On a case by case basis, fewer trials may be acceptable when additional circumstances can be taken into account, for example, undetected residues following treatment at exaggerated rates." (2015 JMPR Report).

With respect to determining trial requirements for a global submission, where a 40% reduction in the number of trials relative to the sum of individual country requirements may be made (OECD, 2009), submitters should not base that reduction on the joint requirements specified in this document. Rather, submitters should consider the requirements specified in DIR2010-05 and OCSPP Guideline 860.1500 simultaneously with the requirements of other regulatory authorities. Alternatively, submitters may consider determining the requirements based on authorities other than Canada and the United States, and then add in the requirements, with no reduction, specified in this document.

Any questions regarding this policy note should be directed to the PMRA's Pest Management Information Service.

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Appendix I Table of distribution of Trial Requirements for Joint Canadian/American Projects

Table 2 Distribution of Trial Requirements for Joint Canadian/American Projects

Crop Group/ Subgroup	Representative Crop	Region														Total # of trials
		1	2	3	4	5	6	7	7A	8	9	10	11	12	13	14	
Root and Tuber Vegetables (CG1)																	
CSG1A, CSG1B	Carrot	1	-	-	-	2	-	-	-	-	-	5	-	-	-	-	8
CSG1A, CSG1B	Radish	-	-	-	-	2	-	-	-	-	-	2	-	-	-	-	4
CSG1A & CG2	Sugar beet	-		-	-	9	-	1	2	-	-	1	3	-	-	-	16
CSG1C	Potato	3	-	-		4	-	-	1	-	1	-	6	-	-	1	16
CSG1D	Sweet Potato	-	3	-	2	2	-	-	-	-	-	1	-	-	-	-	8
Leaves of Root and Tuber (CG2)																	
CG2	Garden or Sugar beet tops	1	-	-	-	2	-	-	-	-	-	1	-	-	-	-	4
CG2	Turnip tops	-	2	-	-	2	-	-	-	-	-	-	-	-	-	-	4
Bulb Vegetables (CG3-07)																	
CSG3-07A	Onion, bulb	-	-	-	-	2	1	-	-	1	-	2	2	-	-	-	8
CSG3-07B	Onion, green	-	-	-	-	2	-	-	-	-	-	2	-	1	-	-	5
Leafy Vegetables (CG 4-13)																	
CSG4-13A	Lettuce (head)	-	-	-	-	2	-	-	-	-	-	6	-	-	-	-	8
CSG4-13A	Lettuce (leaf)	-	-	-	-	2	-	-	-	-	-	6	-	-	-	-	8
CSG4-13A	Spinach	-	1	-	-	2	1	-	-	-	-	4	-	-	-	-	8
CSG4-13B	Mustard Green	-	2	-	-	2	-	-	-	-	-	-	-	-	-	-	4
Brassica Head and Stem Vegetables (CG5-13)																	
CG5-13	Broccoli	-	-	-	-	2	-	-	-	-	-	6	-	-	-	-	8
CG5-13	Cauliflower	-	-	-	-	2	-	-	-	-	-	6	-	-	-	-	8
CG5-13	Cabbage	2	2	-	-	2	-	-	-	-	-	2	-	-	-	-	8
Legume Vegetables (Succulent or Dried) (CG6)																	
CSG6A	Pea, Edible-podded	-	-	-	-	-	-	-	2	-	-	1	2	-	-	-	5
CSG6A	Bean, Edible-podded	-	1	1	-	5	-	-	-	-	-	-	1	-	-	-	8
CSG6B	Peas, Succulent shelled	-	-	-	-	5	-	-	-	-	-	-	3	-	-	-	8
CSG6B	Bean, Succulent shelled	-	2	1	1	2	1	-	-	-	-	1	-	-	-	-	8
CSG6C	Pea, Dry	-	-	-	-	-	-	4	-	-	-	-	1	-	-	3	8
CSG6C	Bean, Dry	-	-	-	-	6	-	3	-	-	-	2	1	-	-	-	12
CG6	Soybean	-	1	-	2	17	-	-	-	-	-	-		-	-	-	20
Fruiting Vegetables (CG8-09)																	
CSG8-09A	Tomato	-	1	1	-	5	-	-	-	-	-	9	-	-	-	-	16
CSG8-09B	Bell pepper	1	1	2	-	2	-	-	-	-	-	2	-	-	-	-	8
CSG8-09B & CSG8-	Nonbell pepper	-	-	-	-	2	-	-	-	2	-	4	-	-	-	-	8

Crop Group/ Subgroup	Representative Crop	Region															Total # of trials
		1	2	3	4	5	6	7	7A	8	9	10	11	12	13	14	
09C																	
CSG8-09C	Eggplant	-	2	-	-	2	-	-	-	-	-	-	-	-	-	-	4
Cucurbit Vegetables (CG9)																	
CSG9A	Muskmelon	-	1	-	-	2	1	-	-	-	-	4	-	-	-	-	8
CSG9B	Cucumber	-	3	1	-	3	-	-	-	-	-	1	-	-	-	-	8
CSG9B	Summer squash	1	2	1	-	2	-	-	-	-	-	1	-	1	-	-	8
Pome Fruit (CG11-09)																	
CG11-09	Apple	4	1	-	-	4	-	-	-	-	-	1	6	-	-	-	16
CG11-09	Pear	1	-	-	-	2	-	-	-	-	-	1	3	1	-	-	8
Stone Fruits (CG12-09)																	
CSG12-09A	Cherry, sweet*	-	-	-	-	1	-	-	-	-	-	2	4	1	-	-	8
CSG12-09A	Cherry, tart*	1	-	-	-	6	-	-	-	-	1	-	-	-	-	-	8
CSG12-09B	Peach	1	2	-	-	2	-	-	-	-	-	3	-	-		-	8
CSG12-09C	Plum	-	-	-	-	2	-	-	-	-	-	6	-	-	-	-	8
*Trials are required for either sweet cherries or tart cherries (including peaches and plums) to support the use on CG 12-09.																	
Berries & Small Fruits (CG13-07)																	
CSG13-07A	Blackberry	-	-	-	-	1	-	-	-	-	-	-	-	3	-	-	4
CSG13-07A	Raspberry	1	-	-	-	1	-	-	-	-	-	-	-	2	-	-	4
CSG13-07B	Highbush blueberry	1	1	-	-	2	-	-	-	-	-	-	-	4	-	-	8
CSG13-07C	Elderberry	2	-	-	-	2	-	-	-	-	-	-	-	-	-	-	4
CSG13-07D and CSG13-07F	Grape	1	-	-	-	2	-	-	-	-	-	12	1	-	-	-	16
CSG13-07D &CSG13-07E	Fuzzy Kiwifruit	-	-	-	-		-	-	-	-	-	2	-	2	-	-	4
CSG13-07G	Strawberry	1	-	1	-	2	-	-	-	-	-	3	-	1	-	-	8
CSG13-07H	Cranberry	3	-		-	3	-	-	-	-	-	-	-	2	-	-	8
Cereal Grains (CG15)																	
CG15	Corn, field	1	-	-	-	17	-	1	-	1	-	-	-	-	-	-	20
CG15	Corn, sweet	1	1	-	-	4	-	-	-	-	-	-	1	1	-	-	8
CG15	Wheat	-	1	-	-	5	1	5	-	2	-	-	2	-	-	4	20
CG15	Barley	-	-	-	-	2		3	1	-	1	-	2	-	-	7	16
Oilseeds (CG20 revised)																	
CSG20A	Rapeseed	-	-	-	-	2	-	2	-	-	-	-	-	-	-	8	12
CSG20B	Sunflower	-	-	-	-	3	-	3	-	1	-	-	-	-	-	1	8
CSG20C	Cottonseed	This crop subgroup was not included in the project as cottonseed is not grown in Canada															
Stalk, Stem, and Leaf Petioles (CG22)																	
CSG22A	Asparagus	-	-	-	-	2	-	-	-	-	-	2	1	-	-	-	5
CSG22B	Celery	-		-	-	2	-	-	-	-	-	6	-	-	-	-	8

Crop Group/ Subgroup	Representative Crop	Region														Total # of trials
		1	2	3	4	5	6	7	7A	8	9	10	11	12	13	14	
Additional Crops requested by Minor Use community & other specialty groups																	
CG1	Ginseng	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	4
Miscellaneous	Hop	-	-	-	-	1	-	-	-	-	-	-	3	1	-	-	5
Miscellaneous	Globe Artichoke	1	-	-	-		-	-	-	-	-	2	-	1	-	-	4
CG13-07	Gooseberry	-	-	-	-	2	-	-	-	-	-	-	-	2	-	-	4
CG3-07	Garlic	-	-	-	-	2	-	-	-	-		2	1	-	-	-	5

Appendix II Table of Percentage Reduction for Joint Canadian/American Projects for Crop Field Trial Requirements

Table 3 Percentage Reduction (% Reduction) in Trial Requirements When Total Country Specific Requirements for United States and Canada are Compared to Total Requirements for a Joint American/Canadian Project

Crop Group/ Subgroup [PMRA ID]	Representative Crops	Number of Crop Field Trials Currently Required by each country			Total # of trials required across US and Canada based on Trial Reduction Project	% Reduction from Current combined US/Canadian Requirements
		CAN	USA	Total for CAN/US		
Root and Tuber Vegetables [CG1]	Carrot	5	8	13	8	38%
	Potato	16	16	32	16	50%
	Radish	2	3	5	4	20%
	Sugar Beet	8	16	24	16	33%
	Sweet Potato	3	8	11	8	27%
Leaves of Root and Tuber Vegetables [CG2]	Garden or Sugar Beet tops	3	3	6	4	33%
	Turnip, tops	2	3	5	4	20%
Bulb Vegetables [CG3-07]	Onion, dry bulb	5	8	13	8	38%
	Onion, green	3	5	8	5	38%
Leafy Vegetables [CG4-13]	Lettuce (head)	5	8	13	8	38%
	Lettuce (leaf)	5	8	13	8	38%
	Spinach	3	8	11	8	27%
	Mustard Greens	2	3	5	4	20%
Brassica Head and Stem Vegetables [CG5-13]	Broccoli	5	8	13	8	38%
	Cauliflower	5	8	13	8	38%
	Cabbage	5	8	13	8	38%
Legume Vegetables (Succulent or Dried) [CG6]	Pea, edible-podded	8	5	13	5	62%
	Bean, edible-podded	5	8	13	8	38%
	Pea, succulent shelled	8	8	16	8	50%
	Bean, succulent shelled	5	8	13	8	38%
	Pea, Dry	8	5	13	8	38%
	Bean, Dry	8	12	20	12	40%
	Soybean	16	20	36	20	44%
Fruiting Vegetables [CG8-09]	Tomato	12	16	28	16	43%
	Bell pepper	5	8	13	8	38%
	Non-bell pepper	3	8	11	8	27%
	Eggplant	2	3	5	4	20%
Cucurbit	Cucumber	5	8	13	8	38%

Crop Group/ Subgroup [PMRA ID]	Representative Crops	Number of Crop Field Trials Currently Required by each country			Total # of trials required across US and Canada based on Trial Reduction Project	% Reduction from Current combined US/Canadian Requirements
		CAN	USA	Total for CAN/US		
Vegetables [CG9]	Muskmelon (cantaloupe)	3	8	11	8	27%
	Summer squash	5	8	13	8	38%
Pome Fruits [CG11-09]	Apple	12	16	28	16	43%
	Pear	5	8	13	8	38%
Stone Fruits [CG12-09]	Cherry, sweet	5	8	13	8	38%
	Cherry, tart	5	8	13	8	38%
	Peach	5	8	13	8	38%
	Plum	3	8	11	8	27%
Berries & Small Fruits [CG13-07]	Blackberry	2	3	5	4	20%
	Highbush blueberry	5	8	13	8	38%
	Raspberry	3	3	6	4	33%
	Elderberry	2	3	5	4	20%
	Grape	5	16	21	16	24%
	Fuzzy Kiwifruit	2	3	5	4	20%
	Strawberry	5	8	13	8	38%
	Cranberry	5	5	10	8	20%
Cereal Grains [CG15]	Barley	12	12	24	16	33%
	Corn, field	16	20	36	20	44%
	Corn, sweet	8	8	16	8	50%
	Wheat	20	20	40	20	50%
Oilseeds [CG20R]	Rapeseed	12	8	20	12	40%
	Sunflower	5	8	13	8	38%
Stalk, Stem, and Leaf Petioles [CG22]	Asparagus	3	5	8	5	38%
	Celery	5	5	10	8	20%
Additional Crops Requested by the Minor Use Community & Specialty Groups	Ginseng	3	3	6	4	33%
	Hop	2	3	5	5	0%
	Globe Artichoke	2	3	5	4	20%
	Gooseberry	2	3	5	4	20%
	Garlic	2	5	7	5	29%

Percentage reduction does not take into consideration any trial requirements in zones common to the United States and Canada (for example, zone 5).
Total number of representative crops: 50
Total number of additional crops: 5

References

1. DIR2010-05 *Revisions to the Residue Chemistry Crop Field Trial Requirements*, 21 December 2010, 16 pages.

2. *Methodology Report – Updating the Number and Location of crop Field Trials for the United States of America*. May 2007. Spatial Analysis and Geomatics Applications (SAGA), Agriculture Division, Statistics Canada. 206 pages.

3. NAFTA *Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada* (2005), 30 pages.

4. OCSPP Guideline 860.1500 (Crop Field Trials), United States Environmental Protection Agency, EPA 712-C-96-183, August 1996, 91 pages.

5. OECD Guideline for the Testing of Chemicals Number 509, September 2009, 44 pages.

6. Pesticide residues in food 2015 – Joint FAO/WHO Meeting on Pesticide Residues, ISSN 0259-2517, 2015, 647 pages.